

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparative Evaluation of High-power Laser versus Anti-Inflammatory Effects of Corticosteroid Injection on Symptoms and Function in Patients with Mild to Moderate Carpal Tunnel Syndrome

Protocol summary

Study aim

Comparison of the effectiveness of high-power laser versus corticosteroid injection in improving the function and symptoms of patients with mild and moderate carpal tunnel syndrome

Design

The study is a randomized, controlled, parallel-group, single-blind trial involving 40 patients. Block randomization with blocks of four was used, and Excel software was employed for randomization.

Settings and conduct

Patients with mild and moderate carpal tunnel syndrome who visit the physical medicine clinics of Imam Khomeini and Sina hospitals during the study period and meet the inclusion criteria will be enrolled in the study. They will be randomly assigned to either the intervention or control group using block randomization method with block size of 4. This study will be conducted in a single-blind manner, such that physicians, and data analysts will be unaware of the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age > 18, Mild to moderate CTS (based on nerve conduction study) Exclusion Criteria: Surgical indication, Neurological disorders, pregnancy, infection, malignancy, Allergy or contraindication to corticosteroids, Prior CTS surgery or corticosteroid injection in the last 6 months

Intervention groups

Intervention: Six sessions of high-power laser therapy were applied to the flexor retinaculum of the affected wrist. The patient sat comfortably with the forearm on the table. Both patient and physician wore protective goggles. The scanner probe was moved back and forth over the area for five minutes. Treatment followed a specific carpal tunnel protocol (30 Hz, 1.5 W, 30 J/cm²), conducted over three weeks, every other day. Control: Standard treatment with a 1 ml injection of 40 mg

triamcinolone at the distal wrist crease

Main outcome variables

Boston Questionnaire Score, Pain and Numbness Severity, Patient Satisfaction, Median Nerve Conduction Study (NCS) Findings

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241228064194N1**

Registration date: **2025-04-20, 1404/01/31**

Registration timing: **prospective**

Last update: **2025-04-20, 1404/01/31**

Update count: **0**

Registration date

2025-04-20, 1404/01/31

Registrant information

Name

Fateme Khosravipour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 936 038 5602

Email address

khosravifahime35@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-05, 1404/02/15

Expected recruitment end date

2025-06-05, 1404/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Evaluation of High-power Laser versus Anti-Inflammatory Effects of Corticosteroid Injection on Symptoms and Function in Patients with Mild to Moderate Carpal Tunnel Syndrome

Public title

High power Laser in carpal tunnel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 18 years mild to moderate carpal tunnel syndrome (CTS) based on nerve conduction study (NCS) findings

Exclusion criteria:

Patients who have surgical indications, such as severe weakness, thenar muscle atrophy, or lack of response to treatment. Concurrent neurological disorders based on electromyography observations, such as polyneuropathy, ulnar neuropathy, proximal median neuropathy, plexopathy, mononeuritis multiplex, cervical radiculopathy. pregnancy infection malignancy patients who have received corticosteroid injections in the past six months. patients with a history of wrist surgery for CTS treatment, allergy to corticosteroids contraindications for corticosteroids

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

randomized (block randomization method with the block size 4 using Excel software), phase 4 on 40 patients

Blinding (investigator's opinion)

Single blinded

Blinding description

This was a single-blind study. A physician (specialist in physical medicine and rehabilitation), who was unaware of the treatment group of each patient, was responsible for the initial electrodiagnostic assessment and for collecting data from all patients (including demographic data, pain intensity [VAS], Boston questionnaire, grip

strength, and electrodiagnostic findings). Another physician performed high-power laser therapy, and a therapist administered the cortisone injections, both of whom were blinded to the patients' group assignments. The patients themselves were not blinded to the treatment they received.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Emam Khomeini complex Hospital

Street address

No.5.Gharib St,Keshavarz Blvd., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2023-08-29, 1402/06/07

Ethics committee reference number

IR.TUMS.IKHC.REC.1402.210

Health conditions studied**1****Description of health condition studied**

carpal tunnel syndrome

ICD-10 code

G56.0

ICD-10 code description

Carpal tunnel syndrome

Primary outcomes**1****Description**

Boston Questionnaire Score

Timepoint

Before the intervention, 2 weeks, 1 month, and 3 months after the completion of the intervention.

Method of measurement

Boston Questionnaire

2

Description

Patient Satisfaction level

Timepoint

Before the intervention, 2 weeks, 1 month, and 3 months after the completion of the intervention.

Method of measurement

Patient Satisfaction Questionnaire

3

Description

Visual Analog Scale for pain and numbness score

Timepoint

Before the intervention, 2 weeks, 1 month, and 3 months after the completion of the intervention.

Method of measurement

Visual Analog Scale for pain and numbness

4

Description

Median Nerve Conduction Study (NCS) Findings

Timepoint

Before the intervention and 3 months after the completion of the intervention.

Method of measurement

Nerve Conduction Study (NCS) device.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients will receive six sessions of high-power laser therapy over three weeks, with a two-day interval between each session, each lasting five minutes, according to the predefined protocol on the Novin high-power laser device (30 Hz frequency, 1.5 W power, and 30 J/cm² dose). The device is calibrated before use and is the same for all patients. Due to the lack of consistency in laser parameters across studies using high-power lasers, we used the preset program for carpal tunnel syndrome (CTS) provided by the device. The session begins with the patient seated in a relaxed position, with the forearm resting on the treatment table. In the main unit of the device, the therapist selects the CTS treatment program. Then, after providing protective glasses for both the patient and therapist, the treatment begins, and the scanner probe is moved back and forth over the flexor retinaculum of the wrist (3 cm proximal and distal to the wrist crease) for five minutes, simultaneously with pedal pressure, which activates the laser. The pedal pressure corresponds to the laser exposure. All these steps are performed by one physician for all patients.

Category

Treatment - Devices

2

Description

Control group: For this group of patients, routine and standard treatment for carpal tunnel syndrome is performed. This treatment includes an injection of 1 mL of triamcinolone (40 mg) in the distal wrist crease.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeini complex hospital

Full name of responsible person

Dr Fateme Khosravipour

Street address

Number 21, Gharib St. Keshavarz Blvd, Vali-e Asr Ave., Tehran , Iran

City

Tehran

Province

Tehran

Postal code

1416643491

Phone

+98 21 6119 2291

Fax

+98 21 6658 1625

Email

Imamhospital@tums.ac.ir

Web page address

<https://ikhc.tums.ac.ir>

2

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Fateme Khosravi pour

Street address

No.5,Hasan Abad Ave, Emam Khomeini .Blvd,Tehran,Iran

City

Tehran

Province

Tehran

Postal code

4691111367

Phone

+98 21 6634 8500

Email

hosp_sina@sina.tums.ac.ir

Web page address

<https://sinahospital.tums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Ramin Kordi

Street address

Number 21, Qods St., Keshavarz Blvd., Tehran
1416753955 Iran

City

Tehran

Province

Tehran

Postal code

1417935840

Phone

+98 21 8898 7381

Fax

+98 21 8898 9664

Email

pajoheshi-ece@sina.tums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Fateme Khosravipour

Position

physical medicine and rehabilitation resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

No.5.Gharib St,Keshavarz Blvd., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 2291

Fax

+98 86 4623 2503

Email

khosravifahime35@gmail.com

Web page address

https://ikhc.tums.ac.ir

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mohadese Azadvari

Position

Associated professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

No.5.Gharib St,Keshavarz Blvd., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1416643491

Phone

+98 912 634 2982

Email

drazadvari@yahoo.com

Person responsible for updating data

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Fateme Khosravipour

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

No.5.Gharib St,Keshavarz Blvd., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Phone

+98 936 038 5602

Email

khosravifahime35@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

"There is no more information available."

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available